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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,957	06/18/2001	Rose Ramon Botella Mesa	229752001300	3466

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EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,957

Applicant(s)

BOTELLA MESA ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7,9,11-15 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7,9,11-15 and 19-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/11/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

This office action is in response to an amendment and a request for continued examination filed 7/12/04. A request for continued examination under 37 CFR 1.114 was filed in this application after Notice of Appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 7/12/04 has been entered. Claims 2-6, 8, 10, 16-18 and 25 have been cancelled. Claims 1, 7, 11, 15 and 23 have been amended. Claims 1, 7, 9, 11-15 and 19-24 are pending in the application.

Information Disclosure Statement

An IDS filed 4/11/02 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

Specification

The substitute specification filed 7/12/04 has been entered.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR

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1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. A replacement sequence listing was received 8/29/01. However, the letter stating that the contents of the sequence listing and the CRF are the same must state that there is no new matter by the submission of the sequence listing and CRF. A new sequence listing, CRF and letter stating that there is no new matter and that the contents of the sequence listing and CRF are the same are required.

Claim Objections

Claims 11-14 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to the claim numbers in the alternative. See MPEP § 608.01(n). Accordingly, the claims not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 9, 11-15 and 19-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The limitation that the nucleotide sequence has at least 70% identity to SEQ ID NO:3 has been added to claim 1 and 7. Applicant has not indicated where support for this limitation is found. The examiner has been unable to find literal support in the originally filed specification for the term "70%" rather applicants disclose that the promoter can have 25% identity to SEQ ID NO:3. Therefore, the limitation of "70%" is impermissible NEW MATTER.

Claims 1, 7, 9, 11-15 and 19-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1, 7 and 15, applicants claim a genus of nucleotide sequences that encode a promoter that directs expression of ACC and is inducible in response to physical stimulation. The recited sequences are set forth in SEQ ID NO:3 or have at least 70% identity to SEQ ID NO:3 or hybridize to SEQ ID NO:3 under stringency conditions of 2X SSC, 0.1% w/v SDS at 45°C or a complementary sequence of nucleotides or are isolated following hybridization of all or part of SEQ ID NO:1 or are portions of SEQ ID NO:3.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a

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combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

Applicants recite a broad and diverse genus of sequences that are set forth in SEQ ID NO:3 or have at least 70% identity to SEQ ID NO:3 or hybridize to SEQ ID NO:3 under stringency conditions of 2X SSC, 0.1% w/v SDS at 45°C or a complementary sequence of nucleotides or are isolated following hybridization of all or part of SEQ ID NO:1 or are portions of SEQ ID NO:3. Functionally, applicants disclose that the promoter is inducible by physical stimuli such as mechanical stress (movement, vibration, air pressure, water stress) and non-mechanical stress (auxins, abscisic acid, salt, environmental stress and chemical induction) (page 28, third paragraph through page 29). Applicants only disclose the sequence of pGEL-1 (SEQ ID NO:3). pGEL-1 comprises the promoter from mung bean ACC synthase that directs expression of a protein encoded by a sequence with 100% identity to SEQ ID NO: 1. Applicants only disclose primer pairs 4 and 5 that are used to isolate the promoter from mung bean, which is reamplified with primer pairs 6 and 7 or 8 and 9. The promoter regions of SEQ ID NO:3 or pGEL-1 are amplified specifically with these primers. Applicants generate a series of seven serial deletions of the mung bean ACC synthase promoter region (page 36). The fragments are relatively active in directing expression of GUS in several plant tissues. However, the activity of the seven fragments in comparison to pGEL-1 is unknown. Furthermore, it is not clear if the activity of the fragments is in response to physical stimulation and therefore, it is not clear that the fragments meet the functional limitations of the claims.

Thus, the structural requirements of sequences that encodes a promoter that functions to direct expression of ACC and that is inducible in response to physical

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stimulation cannot be envisioned. Applicants generate a series of seven serial deletions of the mung bean ACC synthase promoter region (page 36). The fragments are relatively active in directing expression of GUS in several plant tissues. However, the activity of the seven fragments in comparison to pGEL-1 is unknown. Furthermore, it is not clear if the activity of the fragments is in response to physical stimulation and therefore, it is not clear that the fragments meet the functional limitations of the claims. By reciting sequences identified by use of a primer that corresponds to all or part of SEQ ID NO:1, and by claiming sequences hybridizing under medium stringency conditions (according to page 13, 6X SSC, 0.1% w/v SDS and 45°C) or that corresponds to a part of SEQ ID NO:1, the relationship between the structure of the sequence and its function becomes unclear.

Neither applicant nor the prior art provide a correlation between “regions” or “portions” or sequences of SEQ ID NO: 3 and their ability to direct expression of ACC synthase or in response to induction. Given the large size and diversity of the recited sequences, the absence of disclosed or art recognized correlations between structure and function and the large number of potential sequences, portions or regions, it must be considered that any functional fragment or mutation must be empirically determined. By disclosing pGEL-1, the applicants have not reduced to practice the claimed invention and the relationship between structure and function is unclear. In an unpredictable art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

Response to Amendment-35 USC 112, first paragraph

Applicants traverse the claim rejections under 35 U.S.C. 35 USC 112, first paragraph on pages 8-9 of the amendment filed 7/12/04. Applicants argue that the claims as amended provide the requisite structural characteristic as well as functional characteristics sufficiently to show one of skill in the art that inventors were in possession of the claimed genus.

Applicant's arguments filed 7/12/04 have been fully considered but they are not persuasive. Applicants have not provided sufficient structural characteristics that a person of skill in the art would be able to identify the recited sequences. By disclosing SEQ ID NO:3 those functions to induce transgene or ACC-1 expression in response to physical stimulation, applicants have disclosed a single species of the claimed genus. While applicants have disclosed seven fragments of SEQ ID NO:3, it is not clear if these fragments meet the functional requirements of the instant invention. Even if the activity of the seven fragments were disclosed, it is not clear that the disclosed fragments provide the means to identify sequences that hybridize to SEQ ID NO:3 under stringency conditions of 2X SSC, 0.1% w/v SDS at 45°C or that hybridize to parts of SEQ ID NO:1. The results of these hybridizations would generate a large and diverse genus of sequences as parts of SEQ ID NO:1 can be as small as one dinucleotide. The structural requirements of SEQ ID NO:3 have not been described such that any member of the recited genus could be identified nor are portions of SEQ ID NO:3 are unknown that have the recited functional requirements. Adequate written description requires more than a mere statement that the sequence is part of the invention and a reference to a potential

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method for isolating it. Therefore, the specification has failed to describe the genes such that the nexus of structure and function is apparent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 7, 9, 11-15 and 19-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 7 are vague and indefinite in that the metes and bounds of the isolated nucleic acid molecule are unclear. As the claim recites an isolated nucleic acid molecule comprising a sequence of nucleotides as set forth in SEQ ID NO:3 **and** either 1) a sequence having 70% identity to SEQ ID NO:3 or 2) a sequence that hybridizes under stringent conditions or 3) a complementary sequence. Furthermore, as recited it appears that only “a complementary sequence” defines a promoter that directs expression of ACC. To the contrary, it appears applicants intend to recite that the nucleotide sequence is any of the four sequences and that any of these sequences define a promoter. It would be remedial to amend the claim to recite this.

Claim 1 is vague and indefinite in that the metes and bounds of “a complementary sequence” are unclear. It is unclear to what complementary refers and how “a complementary sequence” can define a promoter.

Claim 15 is vague and indefinite in that the metes and bounds of the term “derived from” are unclear. It is unclear the nature and number of steps required to

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obtained a “derivative” of a promoter. The term implies a number of different steps that may or may not result in a change in the functional characteristics of the portion from the source that it is “derived from”. It would be remedial to amend the claim language to use the term “obtained from”, which implies a more direct method of acquiring promoters.

Response to Amendment-35 USC 112, second paragraph

Applicants traverse the claim rejections under 35 U.S.C 112, second paragraph on page 8 of the amendment filed 7/12/04. Applicants argue that the modular promoter of claim 15 can comprise any sequence that is derived by any degree from SEQ ID NO:3 and by any known method.

Applicant's arguments filed 7/12/04 have been fully considered but they are not persuasive. While applicants state that any method of deriving can be used and the promoter sequences can be derived to any degree, the metes and bounds of a promoter derived from SEQ ID NO:3 derived by any degree by any known method are unknown. By reciting that the sequences are “derived from” SEQ ID NO:3, the end product is unknown.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Knox et al (Molecular and Cellular Biology, June 1991, pages 2946-2951; see entire document).

Knox et al teach a chimeric promoter which comprises at least a portion that is derived from SEQ ID NO:3. The tata box of SEQ ID NO:3 is a portion of SEQ ID NO:3 that can be said to be in the chimeric promoter shown in figure 1.

Conclusion

Claims 1, 5, 7, 9, 10, 15 and 19-25 are rejected.

Claims 11-14 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from a multiple dependent claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

August 24, 2004


GERRY LEFFERS
PRIMARY EXAMINER